

**Amendment**

Applicant: Northrup III et al.

Serial No.: 09/800,613

Filed: March 7, 2001

Docket No.: M104.120.102

Title: DEVICE FOR CREATING AN ANASTOMOSIS, INCLUDING PENETRATION STRUCTURE AND  
EVERSION STRUCTURE

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**REMARKS**

Claims 1, 4-5, 8-19, 21-26, and 30-40 are pending. By this Amendment, claims 1, 4-5, 8-9, 11-14, 16-17, 19, 21-22, and 30 are amended, claims 2-3, 6-7, 20 and 27-29 are cancelled, and new claims 36-40 are added.

**Previously Filed Request for Approval of Drawing Changes**

Attention is directed to the Request for Approval of Drawing Changes filed May 28, 2002. The Commissioner is requested to review and approve the changes set forth in the Request.

**35 U.S.C. § 112, Second Paragraph Issues**

The November 19, 2003 Office Action rejected claims 3-4, 16-17, and 20-21 under 35 U.S.C. § 112, second paragraph. By this Amendment, these claims are amended and/or cancelled to overcome the 35 U.S.C. § 112, second paragraph rejection. Applicants submit that the claims satisfy 35 U.S.C. § 112, second paragraph.

**35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) Issues**

The November 19, 2003 Office Action rejected claims 1-5, 8-13, 15-17, 19-26, 30, and 32-35 under 35 U.S.C. § 102(b) over Miller (U.S. Patent No. 2,254,620) and claims 14, 18, and 31 under 35 U.S.C. § 103(a) over Miller. Applicants respectfully traverse these rejections.

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**Claim 1 and Dependent Claims**

Miller fails to anticipate the claimed subject matter or render it obvious. Turning to claim 1, for example, claim 1 recites that the everting elements are constructed and arranged such that they contact the anatomical structures at contact locations, and the spacing elements such that they contact the anatomical structures at contact locations. When the staple body is bent, the spacing-element contact locations are closer to each other than the everting-element contact locations are to each other - such that the apposed everting elements are generally prevented from crushing the anatomical structures. Support for embodiments of the invention including these features is found in e.g. Figure 6 of the application, page 8, lines 13-15, and page 12, lines 15-17.

Miller, on the other hand, shows in e.g. Figure 4 that spacing elements (as named in the Office Action) 19, 20 are not closer to each other at locations of anatomical-structure contact than are everting elements (as named in the Office Action) 8, 9 / 30, 31. Further, there is no teaching or suggestion in Miller to modify Miller's device to include this feature. Miller fails to recognize the advantages afforded by Applicants' structure, including the claimed apposed everting elements being generally prevented from crushing the anatomical structures. Moreover, Miller contains no disclosure of an anastomosis between two anatomical structures, and no disclosure of an everted anastomosis. Applicant submits that claim 1 defines patentable subject matter.

Claims depending from claim 1 recite additional features, not taught or suggested in the prior art. For example, claim 4 recites that the spacing elements are closer to a bend in the staple

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body than the everting elements. Claim 5 defines that an inner radius defined by the spacing elements is smaller than an outer radius defined by the everting elements, the radii being taken from the bend in the staple. Claim 11 recites that the penetrating element is constructed to penetrate all of the at least two anatomical structures. Claim 12 recites that the penetrating element is disposed at only one end of the staple body. Claim 13 defines a general T-shape at one end of the staple and a general L-shape at another end of the staple, support for these features being provided in e.g. Figures 2, 4, 8 and 9. Claim 14 recites one everting element being aligned with the staple body and one other everting element being centered on the staple body such that the staple is asymmetric; Miller and the other references fail to teach or suggest these or the other features recited in the dependent claims.

Applicants submit that claim 1 and its dependent claims define patentable subject matter.

**Claim 19 and Dependent Claims**

Claim 19 recites that when the staple body is bent about a bend thereof and around the cut ends of the anatomical structures, the recited means for spacing are disposed closer to the bend than the means for everting, and the means for everting are disposed closer to a lumen of the anastomosis than the means for spacing. Support for embodiments of the invention including these features is found in e.g. Figure 5 and the supporting text. In Miller, on the other hand, elements 19 and 20 (called “means for spacing” in the Office Action) are disposed farther away from the bend of the disclosed clip than elements 8, 9 (called “means for everting” in the Office Action). There is no teaching or suggestion to modify Miller’s structure to include the claimed

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features. Additionally, Miller contains no disclosure of an anastomosis between two anatomical structures, and no disclosure of means for everting to form an everted anastomosis, as claimed.

Claims depending from claim 19 recite additional features, not taught or suggested in the prior art. Claim 21, for example, recites means for penetrating that extends from one of the anatomical structures into one other of the anatomical structures. Miller's elements 21, 23, on the other hand, extend into only one anatomical structure.

Applicants submit that claim 19 and its dependent claims define patentable subject matter.

Claim 22 and Dependent Claims

Claim 22 recites a single penetrating element for penetrating the recited anatomical structures. Support for embodiments of the invention including these features is found in e.g. Figures 2-6 and the supporting text. Miller's clip, on the other hand, contains multiple elements 21, 23, etc. instead of a single penetrating element. Miller contains no teaching or suggestion to eliminate all of its spiculas 21-24, for example, and in fact doing so likely would destroy the operability of Miller's device. The dependent claims recite additional features, not taught or suggested by the prior art. Applicants submit, therefore, that claim 22 and its dependent claims define patentable subject matter.

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**Claim 30 and Dependent Claims**

Claim 30 recites penetration structure being disposed closer to the recited bend in the device than any portion of the eversion structure is disposed to the bend when the device is in the closed position. Support for embodiments of the invention including these features is found in e.g. Figures 5-6 and the supporting text. In Miller, on the other hand, elements 21, 23 are not so disposed, and there is no teaching or suggestion in Miller to include these features. Moreover, Miller contains no disclosure of an anastomosis of two anatomical structures. The claims depending from claim 30 recite additional features, not taught or suggested by the prior art. Applicants submit that claim 30 and its dependent claims define patentable subject matter.

**Claim 36 and Dependent Claims**

Claim 36 recites a generally cylindrical staple body, and everting elements of generally the same length, one of the everting elements being constructed to protrude from the staple body more than another of the everting elements, among other features. Support for embodiments of the invention including these features is found in e.g. Figures 2-6 and the supporting text. Miller fails to teach or suggest these features. Moreover, Miller contains no disclosure of an everted anastomosis of two anatomical structures. The claims depending from claim 36 recite additional features, not taught or suggested by the prior art. Applicants submit that claim 36 and its dependent claims define patentable subject matter.

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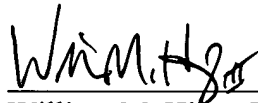
Conclusion

In view of the foregoing, Applicants submit that this application is in condition for allowance. Favorable reconsideration and prompt allowance are requested. The Commissioner is hereby authorized to grant any extensions of time and to charge any fees under 37 C.F.R. § 1.16 and § 1.17 that may be required during the entire pendency of this application, or to credit any overpayment, to Deposit Account No. 500471.

The Examiner is invited to telephone the undersigned to advance prosecution.

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Respectfully submitted,

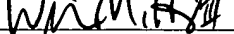


William M. Hienz III  
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*Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 500471.*

CERTIFICATE UNDER 37 C.F.R. 1.8:

The undersigned hereby certifies that this paper or papers, as described herein, are being deposited in the United States Postal Service, as first class mail with sufficient postage, in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 19<sup>th</sup> day of April, 2004.

By   
Name: William M. Hienz III